



December 4, 2020

The Hon. Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

2020 BOARD OF DIRECTORS

Executive Committee

Diane Paloma, MBA, PhD
Chairperson

Marc E. Chow, MS
Vice Chairperson

Chuen L. Yee, MD
Secretary

Kealoha Fox, MA, PhD
Treasurer

Walter Tsou, MD, MPH
Immediate Past Chair

Misun C. Kim, MS

Oliver J. Kim, JD, LLM

Gail Mukaihata Hannemann
President

Juliet K. Choi, Esq.
CEO

Sheri Hamamoto Boyle
PhD, MSW

Jacob Filsemanu Jr., MPH

Sohini Gupta, Esq.

Chang Rim Na, MD, MPH

Jennifer "Jae" Requiro

Neal Shah, JD, MPH

Payal Shah, Esq.

Headquarters

One Kaiser Plaza Suite 850
Oakland, CA 94612
Main 415-954-9988
Fax 510-419-0263
www.apiahf.org

Washington D.C. Office

1629 K Street N.W. Suite 400
Washington, D.C. 20006
Main 202-466-7772
Fax 202-466-6444

National Advocates for Asian
American, Native Hawaiian &
Pacific Islander Health

**Re: RIN 0991-AC24 Securing Updated and Necessary Statutory Evaluations
Timely**

Dear Secretary Azar:

I am writing on behalf of the Asian & Pacific Islander American Health Forum (APIAHF) in response to the Department of Health and Human Services (HHS) proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely" (hereinafter referred to as the "Regulations Rule").

APIAHF is the nation's leading health policy organization working to advance the health and well-being of over 20 million Asian Americans, Native Hawaiians and Pacific Islanders (AANHPI) across the U.S. and territories. APIAHF works to improve access to and the quality of care for communities who are predominately immigrant, many of whom are limited English proficient, and may be new to the U.S. health care system or unfamiliar with private or public coverage. We have longstanding relationships with over 100 community-based organizations across 34 states and the Pacific, to whom we provide capacity building, advocacy and technical assistance. Since 2012, APIAHF and partners have worked to outreach to, educate and enroll 1 million consumers through Action for Health Justice (AHJ), a national collaborative of more than 70 AANHPI national and local community-based organizations and health centers.

As such, we have a strong understanding of the needs and barriers experienced by AANHPI communities across the country and the community based organizations working with them, and the impact that changes outlined in the proposed rule would have on those individuals and communities.

The proposed rule would retroactively impose an expiration provision on most HHS regulations, and establish "assessment" and "review" procedures to determine which, if any, regulations should be retained or revised. The Regulations Rule is an ill-conceived proposal that would create tremendous administrative burden for HHS and would wreak havoc across a broad swath of Department programs and regulated entities from Medicaid and Medicare to Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We also strongly object to the truncated 30-day comment period which is insufficient for a rule of this broad scope with potentially harmful effects. Due to the administrative burdens imposed by the proposed rule, it would divert critical resources from HHS responding to the nation's health, particularly during this COVID-19 national emergency. **As such, we urge HHS to immediately withdraw this proposed rule.**

I. The proposed rule would create tremendous administrative burden for HHS.

HHS asserts that the Regulations Rule will promote “accountability, administrative simplification [and] transparency. . . .”¹ In fact, the proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly \$26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required reviews.² Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.³ However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise.

The Regulations Rule would adversely affect HHS’ ability to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification. In addition, several regulations implementing important parts of the Affordable Care Act (ACA) are approaching their ten-year anniversary, like the Medicaid cost-sharing rule. Regulations like these would need to be reviewed within the next two years, or they would expire. However, the underlying law still exists, even if the regulations expire. Without the cost-sharing rule, states would not have clear guidance on how to implement cost-sharing amounts.

For example, communities, advocates and covered entities rely upon established rules that are critical to implementing federal law, including the Summary of Benefits and Coverage regulation under the ACA and several regulations implementing the ACA’s market reforms.

Especially during crisis situations like COVID-19, it is critically important that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs.

II. The current rule would wreak havoc across all HHS programs.

Regulations play an important role in implementing HHS policies and programs including safety net programs such as Medicaid and the Children’s Health Insurance Program (CHIP), which provide health coverage for over 75.5 million people, including 36.6 million children and over 2,376,800 Asian Americans, Native Hawaiians, and Pacific Islanders on Medicaid. A strong regulatory framework provides states the clarity they need to run these programs on a day-to-day basis, gives providers and managed care plans guidance as to their obligations, and explains to beneficiaries what their entitlement means. This is particularly of concern for communities including AANHPIs and other immigrant populations who may be new to the U.S. health care system and its complexities. For example, through APIAHF’s partnerships with community-based organizations nationwide, we have heard several stories of partners sharing that community members did not know what coverage options were available to them, how their civil rights were protected by federal law and how to enforce those rights. The

¹ 85 Fed. Reg. 70104.

² 85 Fed. Reg. 70116.

³ 85 Fed. Reg. 70112. To be specific, HHS states that “because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480.” *Id.*

Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process and thus create chaos for advocates and the general public.

The bigger danger posed by the Regulations Rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time consuming review process would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies.

For example, arbitrary removal of key regulations governing the Medicaid, CHIP or the ACA could create chaos about federal minimum standards, impacting not only advocates and the public, but state health officials as well. Multiple insurance affordability programs including Medicaid and CHIP rely on regulations at 42 C.F.R. § 435.603 to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. If this regulation were to simply disappear, programs would be free to redefine MAGI household and income counting rules, with no standards, consistency, or accountability. Arbitrarily rescinding large swaths of regulations would wreak havoc in HHS programs, leading to untold harm to the millions of people who rely on those programs.

III. The proposed rule is unnecessary and HHS does not have the authority to propose automatic expiration dates on almost all regulations.

The Regulations Rule claims that automatic expiration dates give HHS the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). First, HHS agencies already commonly update regulations when needed. For example, in 2002 the Centers for Medicare & Medicaid Services (CMS) promulgated new regulations implementing statutory changes to Medicaid managed care.⁴ In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.⁵ CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.⁶ This administration undertook further rulemaking to revise Medicaid managed care regulations, to “relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of

⁴ CMS, *Medicaid Program; Medicaid Managed Care: New Provisions*, RIN 0938–AK96, 67 Fed. Reg. 40989 – 41116 (June 14, 2002), <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms2104f.pdf>.

⁵ CMS, *Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules*, RIN 0938–AS25, 80 Fed. Reg. 31098–31296 (June 1, 2015), <https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>.

⁶ CMS, *Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Final Rule*, RIN 0938–AS25, 80 Fed. Reg. 27498–27901 (May 6, 2016), <https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>.

care.”⁷ CMS annually publishes the Notice of Benefit and Payment Parameters Regulation governing plans in the ACA’s marketplaces. HHS’ contention that it needs to “incentivize” regulation review by imposing a mandatory rescission is simply not supported by the facts.⁸

Further, the RFA requires each agency to publish “a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.”⁹ However, nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.

In fact, this proposal is contrary to the Administrative Procedure Act’s (APA) requirements for rulemaking. In the APA, Congress established clear procedures and standards for agencies seeking to modify or rescind a rule. The APA requires agencies to go through the same rulemaking process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.¹⁰

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would have expired.¹¹ We do not dispute that federal agencies can later amend existing regulations. However, the Regulations Rule would modify thousands of separate, distinct rules across HHS in a single stroke, in violation of the APA. HHS’ attempt to apply a blanket amendment to 18,000 regulations violates the APA’s requirements that review of an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend.

Conclusion

The Regulations Rule would destroy duly promulgated regulations by retroactively imposing an arbitrary end date to those duly promulgated regulations. This rule is unnecessary, will wreak havoc in current HHS programs, and will tie the hands of the incoming Administration by detracting from critical issues like the COVID-19 pandemic to undertake this time-consuming process. It will create chaos for advocates and the general public who will be confused about their rights, federal program obligations and how to enforce them. As such, we strongly oppose this rule and urge HHS to withdraw it immediately. Thank you for the opportunity to submit comments on the proposed rule.

⁷ CMS, *Medicaid Program; Medicaid and Children’s Health Insurance Program (CHIP) Managed Care (Final Rule)*, RIN 0938–AT40, 85 Fed. Reg. 72754–72844, 72754 (Nov. 13, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-11-13/pdf/2020-24758.pdf>.

⁸ 85 Fed. Reg. 70099, 70106.

⁹ 5 U.S.C. 610(a) (In the case of the RFA, periodically is defined as 10 years, unless such review is not feasible, in which case the review can be extended another 5 years).

¹⁰ 5 U.S.C. § 551(5); *see also* Maev P. Carey, Specialist in Government Organization and Management, *Can a New Administration Undo a Previous Administration’s Regulations?*, Congressional Research Service (Nov. 21, 2016), <https://fas.org/sgp/crs/misc/IN10611.pdf> (“In short, once a rule has been finalized, a new administration would be required to undergo the rulemaking process to change or repeal all or part of the rule.”); Office of Information and Regulatory Affairs, Office of Management and Budget, *The Reg Map 5 (2020)* (noting that “agencies seeking to modify or repeal a rule” must follow the same rulemaking process they would under the APA).

¹¹ 85 Fed. Reg. 70104, fn 85 & 86, citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively.

Please do not hesitate to contact my staff at policy@apiahf.org if you have any questions or need any further information.

Sincerely,

A handwritten signature in black ink, appearing to read 'JK Choi', with a small flourish at the end.

Juliet K. Choi
Chief Executive Officer
Asian & Pacific Islander American Health Forum